PCT/JP2003/008192

Translation

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference S-561WO	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/JP2003/008192	International filing date (*day/month/year*) 27 June 2003 (27.06.2003)	Priority date (*day/month/year*) 28 June 2002 (28.06.2002)
International Patent Classification (IPC) or national classification and IPC C07D 239/42, 401/04, A61K 31/505, 31/506, A61P 35/02, 43/00		
Applicant NIPPON SHINYAKU CO., LTD.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 4 sheets, including this cover sheet.

☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of _____ sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
14 November 2003 (14.11.2003)	20 February 2004 (20.02.2004)
Name and mailing address of the IPEA/JP Facsimile No.	Authorized officer Telephone No.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/JP2003/008192

I. Basis of the report

1. With regard to the **elements** of the international application:*

☒ the international application as originally filed

☐ the description:

pages _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

☐ the claims:

pages _____, as originally filed
pages _____, as amended (together with any statement under Article 19
pages _____, filed with the demand
pages _____, filed with the letter of _____

☐ the drawings:

pages _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

☐ the sequence listing part of the description:

pages _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language _____ which is:

☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).

☐ the language of publication of the international application (under Rule 48.3(b)).

☐ the language of the translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

☐ contained in the international application in written form.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☐ furnished subsequently to this Authority in computer readable form.

☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages _____

☐ the claims, Nos. _____

☐ the drawings, sheets/fig _____

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* *Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rule 70.16 and 70.17).*

** *Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.*

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/JP 03/08192

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1-8	YES
	Claims		NO
Inventive step (IS)	Claims		YES
	Claims	1-8	NO
Industrial applicability (IA)	Claims	1-8	YES
	Claims		NO

2. Citations and explanations

Document 1: WO 02/22597 A

The invention set forth in claims 1-8 does not involve an inventive step in the light of document 1 cited in the international search report. Document 1 discloses N-phenyl-2-pyrimidine-amine derivatives represented by general formula (I), which are useful as anti-cancer agents. The compounds that are set forth in the present application are similar to said derivatives in terms of chemical structure; therefore, they could easily have been conceived of by a person skilled in the art. Furthermore, the compounds that are set forth in the present application cannot be said to exhibit superior characteristics in terms of anti-cancer activity or the like in comparison to the compounds that are specifically disclosed in document 1 on the basis of the disclosures in the description of the present application.

In the written response, the applicant asserts that document 1 "does not make any disclosures pertaining to the results of a test of the bcr-abl inhibiting activity, and only cites the document (Nature Medicine, 2, 56-566, 1996). Therein, said document merely indicates the bcr-abl inhibiting activity of...(omission)...STI571. In addition, document 1 indicates that the compounds disclosed therein

exhibit characteristics wherein the half life in the blood is longer and metabolization is more difficult in comparison to STI571, which is evidence to suggest the patentability of said compounds," and "the description of the present application clearly indicates that the compounds set forth in the present application exhibit superior characteristics in comparison to STI571;" therefore, "the compounds set forth in the present application are thought to be similar to STI571 in terms of pharmacological activity, while being superior to the compounds that are specifically disclosed in document 1."

However, if the compounds disclosed in document 1 exhibit a longer half life in the blood and are more difficult to metabolize in comparison to STI571, then it is thought that these compounds may be superior to STI571 as anti-cancer agents; therefore, the compounds that are disclosed in document 1 cannot be said to merely be similar to STI571 in terms of pharmacological activity on the basis of the disclosures of document 1. Consequently, the assertion by the applicant that the "compounds set forth in the present application are thought to be similar to STI571 in terms of pharmacological activity, while being superior to the compounds that are specifically disclosed in document 1" is not applicable.